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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,454	01/20/2006	Sabine Pfeffer	PA/4-33291A/USN	9885
67283 7590 03/31/2009 MONTGOMERY, MCCrackEN, WALKER & RHOADS, LLP 123 SOUTH BROAD STREET AVENUE OF THE ARTS PHILADELPHIA, PA 19109				
EXAMINER				
POWERS, FIONA				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
03/31/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,454

Applicant(s)

PFEFFER ET AL.

Examiner

Fiona T. Powers

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 1/20/06, 4/13/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1 to 8) in the reply filed on December 23, 2008 is acknowledged.

Claims 10 to 16 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 23, 2008.

Information Disclosure Statement

Receipt is acknowledged of the information disclosure statements filed January 20, 2006 and April 13, 2006 which have been entered in the file. The references cited therein have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 to 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 to 7 claim "a crystalline modification A of tegaserod hydrogen maleate". The use of "a" implies that there is more than one crystalline modification A. However, the specification only prepares one compound that is crystalline modification A of tegaserod hydrogen maleate.

To overcome this rejection, "A" (first occurrence) should be deleted from the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 to 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Parthasaradhi et al. (US 2005/0119328), cited.

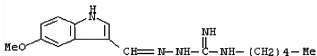
Applicants claim a crystalline modification A of tegaserod hydrogen maleate. Tegaserod hydrogen maleate is also known as tegaserod maleate. See the Registry file information shown below.

Art Unit: 1626

RN 189188-57-6 REGISTRY
ED Entered STN: 22 May 1997
CN Hydrazinecarboximidamide, 2-[(5-methoxy-1H-indol-3-yl)methylene]-N-pentyl-, (2Z)-2-butenedioate (1:1) (CA INDEX NAME)
OTHER CA INDEX NAMES:
CN Hydrazinecarboximidamide, 2-[(5-methoxy-1H-indol-3-yl)methylene]-N-pentyl-, (Z)-2-butenedioate (1:1)
OTHER NAMES:
CN HTF 919
CN SDZ-HTF 919
CN Tegaserod hydrogen maleate
CN Tegaserod maleate
CN Zelnac
CN Zelnorm
FS STEREOSEARCH
MF C16 H23 N5 O . C4 H4 O4
SR CA
LC STN Files: ADISINSIGHT, ANABSTR, BIOSIS, BIOTECHNO, CA, CAPLUS, CBNB, CHEMCATS, CSChem, DDFU, DRUGU, EMBASE, INSPATENTS, IMSRESEARCH, IPA, MRCK*, PHAR, PROUSDDR, PS, SYNTHLINE, TOXCENTER, USAN, USPAT2, USPATFULL
(*File contains numerically searchable property data)

CM 1

CRN 145158-71-0
CMF C16 H23 N5 O



CM 2

CRN 110-16-7
CMF C4 H4 O4

Double bond geometry as shown.



PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT

113 REFERENCES IN FILE CA (1907 TO DATE)
113 REFERENCES IN FILE CAPLUS (1907 TO DATE)

Parthasaradhi et al. disclose the claimed crystalline modification A of tegaserod hydrogen maleate and pharmaceutical compositions thereof. Note paragraphs [0006], [0007] and claims 1, 2, 15 and 16. Note in particular that the X-ray powder diffraction pattern peaks for crystalline tegaserod maleate Form I of the reference shown in paragraph [0007] and claim 1 is essentially the same as that of instant claim 3. Since a compound and its properties are inseparable, the crystalline tegaserod maleate Form I disclosed in the reference is the same as that of the instant claims.

The references made of record and not relied upon show the state of the art or are equivalent to the reference relied upon.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be

reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fiona T. Powers/
Primary Examiner, Art Unit
1626

ftp
March 27, 2009